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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---------------------------|---------------------|------------------|
| 10/729,837  | 12/04/2003  | Manne Satyanarayana Reddy | BULK 3.0-033        | 8513             |
| 45776   | 7590        | 05/02/2006                | EXAMINER            |                  |
| DR. REDDY'S LABORATORIES, INC.<br>200 SOMERSET CORPORATE BLVD<br>SEVENTH FLOOR,<br>BRIDGEWATER, NJ 08807-2862 |             |                           | SACEY, EBENEZER O   |                  |
|   |             |                           | ART UNIT            | PAPER NUMBER     |
|   |             |                           | 1626                |                  |

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/729,837

Applicant(s)

REDDY ET AL.

Examiner

EBENEZER SACKY

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-56 are pending.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, and 33-34 are, drawn to an amorphous form of ziprasidone hydrochloride and method of using the compound in treating psychosis, classified in class 544 and 514, in various subclasses.
- II. Claim 17 is, drawn to a process for making ziprasidone hydrochloride, classified in class 544, subclass 279+.
- III. Claims 18-21 are, drawn to a first process for making an amorphous form of ziprasidone hydrochloride, classified in class 544, subclass 279+.
- IV. Claims 22-32 are, drawn to a second process for making an amorphous form of ziprasidone hydrochloride, classified in class 544, subclass 279+.
- V. Claims 35-46 and 56, drawn to crystalline form of ziprasidone and method of treating psychosis using the compound, classified in class 544 and 514, in various subclasses.
- VI. Claims 47-55 are, drawn to a process for preparing crystalline form of ziprasidone and composition containing the crystalline form of ziprasidone, classified in class 544 and 514, in various subclasses.

The inventions are distinct, each from the other because of the following reasons:  
Groups I-VI are drawn to distinct processes of preparing ziprasidone in various forms of the compounds as demonstrated by the different reactive steps, reactants and X-ray

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diffraction patterns. Additionally, the inventions of Groups I-VI are independent and distinct because there is no patentable co-action among the various groups and a reference anticipating one member will not necessarily render another obvious.

Applicants should note that patentability of product by process claims are based on the product and not the process. Thus, claims 33 and 34 have been added to Group I.

In addition, because of the different classes and subclasses and divergent subject matter, in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, for the reasons given above, the restriction set forth is proper because it would constitute an undue burden on the examiner to examine all of the inventions in this application.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Robert A. Franks on 04/26/06 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is

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(571) 272-1600.

EOS

April 29, 2006

A handwritten signature in black ink, appearing to read "Joe McKane", written over a horizontal line.

Joseph K. McKane

Supervisory Patent Examiner

Art Unit 1626, Group 1600

Technology Center 1